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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/755,996

01/13/2004

Peter M. Bonutti

780-A03-021-5

1472

33771 7590 12/29/2006
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GUTMAN, BONGINI, & BIANCO P.L.
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/29/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/755,996	Applicant(s) BONUTTI, PETER M.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,13,15,19-22 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,13,15,19,24 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 20-22 and 25-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 22 is objected to because of the following informalities: In claim 22, the phrase "fasteners means" would be more clear if recited "first and second fasteners means". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-9, 13, 15, 19, 24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Kovaleva et al. (U.S. Patent No. 4,298,993).

Stone discloses an implantable device for changing the spatial relationship between first and second bones comprising a body (see FIG. 4a), wherein the body includes bone-contacting first and second major planar surfaces, and a side surface there between and wherein one major surface tapers to form a pointed edge with the other major surface. The body has an open cellular structure to provide cavities in which bone can grow through (col. 6, lines 34-36). The body is made of a biocompatible

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metallic material (col. 6, lines 44-46). At least some of the cavities contain a bone growth promoting material (col. 7, lines 8-14). A portion of the side surface has a configuration corresponding to at least a section of an outer side surface of one of the first and second bones.

Stone discloses the claim invention except for the device being coated with a bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, and a first channel extending through the first major surface and side surface, and a screw angularly disposed in the first channel.

Michelson discloses using a coating of bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, in order to promote bioactive fusion (col. 9, lines 20-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with the coating of Michelson in order to promote bioactive fusion.

Kovaleva et al. discloses an implantable device including a first channel extending through the first major surface and side surface, and a screw angularly disposed in the first channel (ref. #11/12) in order to fix the implant to the bone, and the screw holes can also be used with a special holder (col. 3, line 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with a first channel extending through the first major surface and side surface, and a screw angularly disposed in the

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first channel in order to fix the implant to the bone, and also to provide holes that can be used with a special holder.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Kovaleva et al. (U.S. Patent No. 4,298.993) and further in view of Jefferies (U.S. Patent No. 4,394,370).

Stone in view of Michelson discloses the claimed invention except for the coating being apatite compositions such as demineralized bone powder and collagen.

Jefferies teaches both demineralized bone powder and collagen as materials to induce the formation of osseous tissue (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the coating of the Stone in view of Michelson and Kovaleva et al. to include demineralized bone powder and collagen in view of Jeffries, since those materials are well known in the art of bone fusion as materials to induce the formation of osseous tissue.

Claims 10 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635), and Kovaleva et al. (U.S. Patent No. 4,298.993) further in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

Stone in view of Michelson discloses open cellular and biocompatible material, including metals, but does not specifically disclose tantalum.

Zdeblick et al. teaches using porous tantalum in implants to allow bone ingrowth.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone in view of Michelson and Kovaleva et al. using tantalum in view of Zdeblick et al. to allow bone ingrowth.

Allowable Subject Matter

Claims 20-22 and 25-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection (see underlined sections above).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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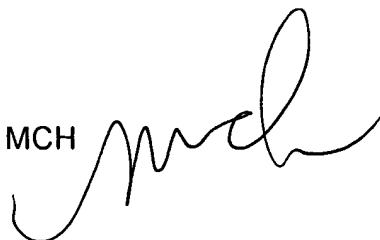
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER